

I hereby certify that, on the date shown below, this correspondence is being:
☒ deposited with the United States Postal Service in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450,
☒ under 37CFR § 1.8(a), with sufficient postage as first class mail, or
☐ under 37CFR § 1.10, as "Express Mail Post Office to Addressee" Mailing Label No.
☐ transmitted by facsimile to the Patent and Trademark Office, Fax Number _____

PATENT

Atty. Docket No.
ALZ5015 R1

J&J Ref.
ALZ5015USANP

CN 27777



Date: June 24, 2004 By: [Signature]
Lois E. Miller

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Samuel Zalipsky et al.

Serial No.: 10/789,489

Filed: February 26, 2004

For: METHOD TO REDUCE LIPOSOME-
INDUCED COMPLEMENT ACTIVATION

Group Art Unit: to be assigned

Examiner: to be assigned

**FIRST SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

Mail Stop: MISSING PARTS
Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. § 1.56 and in accordance with 37 C.F.R. §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. § 1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under § 1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or

before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with
☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application

has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i).

☒ There are no listed references which are not in the English language.

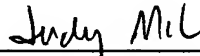
☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,



Attorney for Applicants

Judy M. Mohr, Reg. No.: 38,563

Tel. No.: 650-564-2867

Fax. No. 650-564-2195

ALZA CORPORATION
c/o Johnson & Johnson
One Johnson & Johnson Plaza, WH3221
New Brunswick, NJ 08933
Customer No.: 27777

Enclosed:

1. References AJ - AQ (8 references)



Substitute for form 1449A-PTO		Application Number	10/789,489
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 1		Filing Date	February 26, 2004
		First Named Inventor	Samuel ZALIPSKY
		Group Art Unit	To be assigned
		Examiner Name	To be assigned
		Attorney Docket Number	ALZ5015USANP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Kind Code ² (if known)	Number			
	AI		5,891,468	MARTIN et al.	04-06-1999	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵				
	AJ	WO	98/18813		Alcon Laboratories / R. Conrow	05-07-2004		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T ²
	AK	HUANG, Shi Kun, et al., <u>STEALTH LIPOSOMES</u> , Ch. 11, pp. 108-100, CRC press, Boca Raton, FL 1995. "Mechanism of Stealth® Liposome Accumulation in Some Pathological Tissues"	
	AL	KUBY, Janus, <u>IMMUNOLOGY</u> , 3 rd Edition, Ch 14, pp. 335-356, W.H. Freeman and Company, 1997. "The Complement System"	
	AM	MILLER, Christina R., et al., <u>Biochemistry</u> , 37:12875-12883, 1998. "Liposome-Cell Interactions in Vitro: Effect of Liposome Surface Charge on the Binding and Endocytosis of Conventional and Sterically Stabilized Liposomes"	
	AN	SZEBENI, Janos et al., <u>Circulation</u> , 99:2302-2309, May 4, 1999. "Hemodynamic Changes Induced by Liposomes and Liposome-Encapsulated Hemoglobin in Pigs - A Model for Pseudoallergic Cardiopulmonary Reactions to Liposomes: Role of Complement and Inhibition by Soluble CR1 and Anti-C5a Antibody"	
	AO	SZEBENI, Janos et al., <u>J. Natl. Cancer Inst.</u> , 90(4):300-306, February 18, 1998. "Complement Activation by Cremophor EL as a Possible Contributor to Hypersensitivity to Paclitaxel: an <i>In Vitro</i> Study"	
	AP	WEBB, Murray S., <u>Biochimica et Biophysica Acta</u> , 1372:272-282, 1998. "Comparison of different hydrophobic anchors conjugated to poly(ethylene glycol): effects on the pharmacokinetics of liposomal vincristine"	
	AQ	ZALIPSKY, Samuel, <u>Eur. Polym. J.</u> , 19(12):1177-1183, 1983. "Attachment of Drugs to Polyethylene Glycols"	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450